K081937

8.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

AUG 29 2008

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This summary was prepared on June 27, 2007.

2. The name of the device is the picoSAT II^{plus} SpO_2 pulse oximetry module and the SpO_2 measurement module in the X2 (M3002A) Multi Measurement Module and M1020B SpO_2 Plug-in Module. Classification names are as follows:

Device Panel	*Classification*	*ProCode*	*Description*
Anesthesiology and Respiratory Therapy (12624)	*§870.2700, II*	*DQA*	*Oximeter*

3. Indicated for use whenever there is a need for monitoring, transport monitoring, recording, and alarming of the physiological parameters arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric and neonatal patients in a hospital environment by health care professionals. X2 (M3002A) Multi-Measurement Module is indicated for transport monitoring outside hospitals.

4. The modified device is substantially equivalent to predicate devices K033715 picoSAT II SpO_2 pulse oximetry module, K021300 M3001A Multi-Measurement Server, K072070 X2 (M3002A) Multi-Measurement Module containing the picoSAT II SpO_2 pulse oximetry module.
5. The modified devices have the same intended use as the legally marketed predicate devices. The devices are intended for monitoring, transport monitoring, recording, and alarming of the physiological parameters arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric and neonatal patients in a hospital environment by health care professionals. X2 (M3002A) Multi-Measurement Module is indicated for transport monitoring outside hospitals.

6. The SpO_2 measurement is based on the absorption of light, which is emitted through human tissue (i.e. index finger). Two light sources transmit red and infrared light through the human tissue. The ratio of the different absorption of the red and infrared light is calculated. The saturation value is defined by the percentage ratio of the oxygenated hemoglobin [HbO_2] to the total amount of hemoglobin [Hb] (SpO_2 = [HbO_2]/([Hb]+[HbO_2]). Out of calibration curves, which are based on controlled hypoxia studies with healthy non-smoking adult volunteers over a specified saturation range (SaO_2 from 70%-100%), the ratio determines the SpO_2 value. The measurement accuracy of SpO_2 in the range of 70% to 100% is between 2% and 4% RMS dependent on the Philips sensor type. The measurement accuracy of pulse rate in the range of 30 bpm to 300 bpm is 2% or 1 bpm (whichever is greater).

7. The modification is a hardware and firmware improvement and reduces the manufacturing costs.

8. The modified devices have the same technological characteristics as the legally marketed predicate devices.

9. The accuracy of the device was validated with all Philips SpO_2 sensors by a controlled desaturation study with CO-Oximeter as a reference. Data of 10 volunteers and at least 20 data samples per volunteer with the data samples spread over the specified accuracy range from 70% to 100% were collected. The controlled desaturation study demonstrates that the accuracy of the subject device with all Philips sensors is within the specified accuracy of 2% to 4% RMS (Root Mean Square) in the measurement range of 70% to 100% oxygen saturation compared to SaO_2 reference values. No adverse events were reported.

10. Verification testing activities were conducted to establish the performance and reliability characteristics of the new device. Testing involved functional level tests and safety testing from the risk analysis. Clinical validation studies were also conducted. All verification and validation activities were successfully completed. The verification and clinical validation results demonstrate that modified device is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2008

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Re: K081937
Trade/Device Name: PicoSAT II^{plus} SpO_2 Pulse Oximetty Module, SpO_2 Measurement Module in the X2(M3002A) Multi-Measurement Module and M1020B SpO_2 Plug-in Module
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 22, 2008
Received: August 25, 2008

Dear Dr. Seher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin, M.D. for //

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081937

Device Name: picoSAT II^{plus} SpO_2 pulse oximetry module, SpO_2 measurement module in the X2 (M3002A) Multi-Measurement Module and M1020B SpO_2 Plug-in Module

Indications for Use: Indicated for use whenever there is a need for monitoring, transport monitoring, recording, and alarming of the physiological parameters arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric and neonatal patients in a hospital environment by health care professionals.

X2 (M3002A) Multi-Measurement Module is indicated for transport monitoring outside hospitals.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081937

Prescription Use yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)